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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,046	11/06/2006	Guguli Abashidze	15447.0001USWO	8865

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
MACAULEY, SHERIDAN R	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,046	ABASHIDZE ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5 and 7-25* is/are pending in the application.

4a) Of the above claim(s) *12-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5 and 7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

1. A response and amendment were received an entered on May 28, 2010. All evidence and arguments have been fully considered. Claims 3, 4, 6 and 26 are cancelled. Claims 1, 2, 5 and 7-25 are pending. Claims 12-25 have been withdrawn due to a previous requirement for restriction. Claims 1, 2, 5 and 7-11 are examined on the merits in this Office action.

Claim Rejections - 35 USC § 112

2. Rejections under 35 USC 112 are withdrawn due to applicant's amendment.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (US Pat. 2,414,290; reference cited in previous action) in view of Szejtli et al. (US 4,529,608; reference cited in previous action) and Bender (US 3.485,920; reference cited in previous action). The claims recite a method of obtaining a medicinal from honey, the method comprising: (a) treating honey thermally at 100-160 degrees C to obtain a solution; (b) settling the solution for 22-26 hours; (c) mixing the settled solution with adsorbent, specifically wherein the absorbent is activated carbon and wherein the ratio of adsorbent to settled solution is 7-100; (d) settling the mixed solution from (c) for 10-14 hours; and (e) filtering the settled mixed solution from (d) to obtain the medicinal from honey in the liquid form, specifically wherein the solution is filtered twice. The claims further recite that the method comprises (f) mixing the liquid from step (e) with a pharmaceutically acceptable auxiliary, such as sodium bicarbonate and wherein the mass ratio of the liquid from (e) and the pharmaceutically acceptable auxiliary is 1:1; and (g) drying and powdering the mixture from (f) to obtain the medicinal in the form of

dry powder. The claims further recite that the mixture is heated between steps (b) and (c).

7. Erickson teaches honey that has been prepared by heating, mixing with an adsorbent (i.e., activated carbon), and filtering the solution to obtain the treated honey preparation (col. 2, lines 24-52). The reference also teaches a method wherein the honey is heated prior to being combined with the activated carbon (col. 2, lines 46-52) and that honey may be heated and settled to allow the solids to precipitate out (col. 3, lines 4-18). The reference also teaches that the honey may be heated at temperatures of about 100 degrees C (col. 3, lines 40-48). The reference does not specifically teach all of the claimed steps in a single method. Erickson also does not specifically teach mixing the liquid medicinal with a pharmaceutically acceptable auxiliary, drying and powdering the mixture to obtain the medicinal as a powder.

8. Szejtli teaches a method of preparing a dried honey powder by preparing a liquid, mixing the liquid with a powder and drying the mixture to produce a powdered product (abstract). The reference teaches that the honey product may be treated at about 100 degrees C (abstract).

9. Bender teaches medicaments comprising honey-based products and a mild, edible base such as sodium bicarbonate (abstract, col. 3, lines 13-30).

10. At the time of the invention, methods for the preparation of honey products using methods similar to the claimed method were know, as taught by Erickson. Although the Erickson reference does not teach all of the claimed steps in a single method to produce the treated honey product, one of ordinary skill in the art would have been able

to combine them with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do so because Erickson teaches that the techniques for the treatment of honey may be combined depending upon the characteristics of the batch of honey (col. 6, lines 38-75). Since Erickson teaches that the combination of various methods will depend upon the quality of the honey, one of ordinary skill in the art would be expected to arrive upon the claimed conditions in the course of routine experimentation. Although Erickson does not teach the drying and powdering of the product, it was further known at the time of the invention that dried honey products could be prepared by methods such as those recited in the claims and that sodium bicarbonate was a useful carrier for honey-based medicaments, as taught by Szejtli and Bender. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed invention because Szejtli teaches that drying in the presence of a powdered carrier helps to preserve the natural honey aroma of the product. Since Erickson is directed to maintaining and processing food-quality honey, one of ordinary skill in the art would have been motivated to further process the honey of Erickson using the methods of Szejtli for preservation. Because both references use similar methods to process the honey, the method could have been combined with a reasonable expectation of success. Further, one of ordinary skill in the art would have recognized that sodium bicarbonate would have been a suitable powder for use with a dried honey product because Bender teaches that the additive is compatible with honey and that it has beneficial medical properties. Furthermore, Erickson teaches that basic components are helpful in the preparation of honey products. Therefore one of ordinary

skill in the art would have recognized that the components could have been used in the combined method with a reasonable expectation of success. It would therefore have been obvious to combine the teachings discussed above to arrive at the claimed invention.

11. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

12. Applicant's arguments filed May 28, 2010 have been fully considered but they are not persuasive. Applicant argues that the cited prior art to not render obvious the claimed invention because Erickson does not teach the treatment of honey at the temperature recited in the claims. However, Erickson teaches that the honey may be treated within a temperature range of which the upper limit is about 100 degrees C. One of ordinary skill in the art would therefore recognize that the honey could be treated at 100 degrees C, which meets the limitations recited in the claims. Furthermore, Szejtli teaches the treatment of honey products at 100 degrees C. Given these teachings, one of ordinary skill in the art would have recognized that, in the combined method of the prior art, the heat treatment could be conducted at a temperature that is within the temperature range recited in the claims.

13. Applicants further argue that the cited references do not render obvious the claimed invention because they do not teach the production of a medicament as recited in the claims. It is submitted that the honey of the prior art would possess at least the

medicinal properties of natural honey, and thus can be considered as a medicament. Further, although applicant argues that the honey prepared by the method of the claims provides an advantage, in that it can be formulated into various pharmaceutical forms, applicant has provided no evidence of this assertion. For instance, applicant argues that the medicinal preparations resulting from the claimed method are able to be used in a form such as a capsule, but has not provided evidence that the powdered forms of the prior art (such as those taught by Szejtli) could not have been prepared in a similar manner.

14. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651